

**UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION) MDL No. 2804
THIS DOCUMENT RELATES TO:) Case No. 1:17-md-2804
Track One Cases) Judge Dan A. Polster
CASE NO. 18-op-45090)
THE COUNTY OF SUMMIT, OHIO;)
SUMMIT COUNTY PUBLIC HEALTH;)
THE CITY OF AKRON; THE CITY OF)
BARBERTON; THE VILLAGE OF)
BOSTON HEIGHTS; BOSTON TOWNSHIP;)
THE VILLAGE OF CLINTON; CPLEY)
TOWNSHIP; COVENTRY TOWNSHIP;)
THE CITY OF CUYAHOGA FALLS; THE)
CITY OF FAIRLAWN; THE CITY OF)
GREEN; THE VILLAGE OF LAKEMORE;)
THE VILLAGE OF MOGADORE; THE)
CITY OF MUNROE FALLS; THE CITY OF)
NEW FRANKLIN; THE CITY OF NORTON;)
THE VILLAGE OF PENINSULA; THE)
VILLAGE OF RICHFIELD; THE VILLAGE)
OF SILVER LAKE; SPRINGFIELD)
TOWNSHIP; THE CITY OF STOW; THE)
CITY OF TALLMADGE; VALLEY FIRE)
DISTRICT; STATE OF OHIO EX REL.,)
PROSECUTING ATTORNEY FOR)
SUMMIT COUNTY, SHERRI BEVAN)
WALSH, THE DIRECTOR OF LAW FOR)
THE CITY OF AKRON, EVE BELFANCE,)
THE DIRECTOR OF LAW FOR THE CITY)
OF BARBERTON, LISA MILLER, THE)
DIRECTOR OF LAW FOR THE CITY OF)
TALLMADGE, MEGAN RABER; THE)
LAW DIRECTOR FOR THE CITY OF)
CUYAHOGA FALLS, RUSS BALTHIS,)
THE LAW DIRECTOR FOR THE CITY OF)
FAIRLAWN, BRYAN NACE, THE LAW)
DIRECTOR FOR THE CITY OF GREEN,)
INTERIM LAW DIRECTOR BILL CHRIS,)
THE LAW DIRECTOR FOR THE CITY OF)
DEFENDANT HBC SERVICE
COMPANY'S ANSWER AND
AFFIRMATIVE DEFENSES TO
CORRECTED SECOND
AMENDED COMPLAINT
DEMAND FOR JURY TRIAL

MOGADORE, MARSHAL M. PITCHFORD,)
THE LAW DIRECTOR FOR THE CITY OF)
MUNROE FALLS, TOM KOSTOFF, THE)
LAW DIRECTOR FOR THE CITY OF NEW)
FRANKLIN, THOMAS MUSARRA, THE)
LAW DIRECTOR FOR THE CITY OF)
NORTON, JUSTIN MARKEY; THE LAW)
DIRECTOR FOR THE CITY OF STOW,)
AMBER ZIBRITOSKY; THE VILLAGE)
SOLICITOR FOR THE VILLAGE OF)
BOSTON HEIGHTS, MARSHAL)
PITCHFORD), THE SOLICITOR FOR)
BOSTON TOWNSHIP, ED PULLEKINS),)
SOLICITOR FOR THE VILLAGE OF)
CLINTON, MARSHAL PITCHFORD, THE)
LAW SOLICITOR FOR COPLEY)
TOWNSHIP, IRV SUGARMAN, THE LAW)
SOLICITOR FOR COVENTRY TOWNSHIP,)
IRV SUGARMAN, THE LAW SOLICITOR)
FOR THE VILLAGE OF LAKEMORE, IRV)
SUGARMAN, THE SOLICITOR FOR THE)
VILLAGE OF PENINSULA, BRAD)
BRYAN, THE LAW SOLICITOR FOR THE)
VILLAGE OF RICHFIELD, WILLIAM)
HANNA, THE SOLICITOR THE VILLAGE)
OF SILVER LAKE, BOB HEYDORN, AND)
THE ADMINISTRATOR & LEGAL)
COUNSEL FOR SPRINGFIELD)
TOWNSHIP, WARREN PRICE,)
)
Plaintiffs,)
)
vs.)
)
PURDUE PHARMA, L.P.; PURDUE)
PHARMA, INC.; THE PURDUE)
FREDERICK COMPANY, INC.; ENDO)
HEALTH SOLUTIONS INC.; ENDO)
PHARMACEUTICALS, INC.; PAR)
PHARMACEUTICAL, INC.; PAR)
PHARMACEUTICAL COMPANIES, INC.)
F/K/A PAR PHARMACEUTICAL)
HOLDINGS, INC.; JANSSEN)
PHARMACEUTICALS, INC.; ORTHO-)
MCNEIL-JANSSEN PHARMACEUTICALS,)
INC. N/K/A JANSSEN)

PHARMACEUTICALS, INC.; / JANSSEN)
PHARMACEUTICA, INC. N/K/A JANSSEN)
PHARMACEUTICALS, INC.; JOHNSON &)
JOHNSON; NORAMCO, INC.; TEVA)
PHARMACEUTICAL INDUSTRIES, LTD.;)
TEVA PHARMACEUTICALS USA, INC.;)
CEPHALON, INC.; ALLERGAN PLC F/K/A)
ACTAVIS PLC; ALLERGAN FINANCE)
LLC, F/K/A/ ACTAVIS, INC., F/K/A)
WATSON PHARMACEUTICALS, INC.;)
WATSON LABORATORIES, INC.;)
ACTAVIS LLC; ACTAVIS PHARMA, INC.)
F/K/A WATSON PHARMA, INC; INSYS)
THERAPEUTICS, INC., MALLINCKRODT)
PLC; MALLINCKRODT LLC; SPECGX)
LLC, AMERISOURCEBERGEN DRUG)
CORPORATION; ANDA, INC.; CARDINAL)
HEALTH, INC.; CVS HEALTH)
CORPORATION; DISCOUNT DRUG)
MART, INC.; HBC SERVICE COMPANY;)
HENRY SCHEIN, INC.; HENRY SCHEIN)
MEDICAL SYSTEMS, INC.; MCKESSON)
CORPORATION; MIAMI-LUKEN, INC.;)
PRESCRIPTION SUPPLY, INC.; RITE AID)
CORPORATION.; RITE AID OF)
MARYLAND, INC.; D/B/A RITE-AID MID-)
ATLANTIC CUSTOMER SUPPORT)
CENTER, INC; WALGREENS BOOTS)
ALLIANCE, INC. A/K/A WALGREEN CO.,)
AND WALMART INC. F/K/A WAL-MART)
STORES, INC.,)
Defendants.)

**DEFENDANT HBC SERVICE COMPANY ANSWER AND AFFIRMATIVE DEFENSES
TO CORRECTED SECOND AMENDED COMPLAINT**

HBC Service Company (“HBC”) by and through its undersigned attorneys, Marcus & Shapira LLC, hereby answers Plaintiffs’ Corrected Second Amended Complaint in the above-captioned action as follows:

1. Paragraph 1 of the Complaint identifies Plaintiffs and Defendants and Plaintiffs’ statements of claims to which no response is required.

2. The averments contained in Paragraphs 25-27 of the Complaint are admitted only insofar as they confer jurisdiction and venue on this Court over HBC.

3. The averments contained in Paragraph 113 of the Complaint are admitted except that Giant Eagle's principal place of business is located in Pittsburgh, Pennsylvania.

4. The averments contained in Paragraphs 2 through 24, 28 through 112, and 114 through 877 of the Complaint are asserted against Defendant(s) other than HBC or denied for lack of knowledge or information sufficient to form a belief as to the truth of the averments, are conclusions of law to which no responsive pleading is required and/or are otherwise generally denied.

FIRST CLAIM FOR RELIEF

Violation of RICO, 18 U.S.C. § 1961 *et seq.* - Opioid Marketing Enterprise (Against Purdue, Cephalon, Janssen, Endo and Mallinckrodt (the "RICO Marketing Defendants"))

5. The First Claim for Relief is asserted against Defendants other than HBC and accordingly, no response to the averments contained in Paragraphs 878 through 905 of the Complaint is required.

SECOND CLAIM FOR RELIEF

Violation of RICO, 18 U.S.C. § 1961 *et seq.* - Opioid Supply Chain Enterprise (Against Defendants Purdue, Cephalon, Endo, Mallinckrodt, Actavis, McKesson, Cardinal and AmerisourceBergen—"RICO Supply Chain Defendants")

5. The Second Claim for Relief is asserted against Defendants other than HBC and accordingly, no response to the averments contained in Paragraphs 906 through 938 of the Complaint is required.

THIRD CLAIM FOR RELIEF

**Violation Of The Ohio Corrupt Practices Act
Ohio Revised Code §§ 2923.31, *et seq.*
(Against Purdue, Cephalon, Janssen, Endo, and Mallinckrodt
(the “Opioid Marketing Enterprise”))**

6. The Third Claim for Relief is asserted against Defendants other than HBC and accordingly, no response to the averments contained in Paragraphs 939 through 949 of the Complaint is required.

FOURTH CLAIM FOR RELIEF

**Violation Of The Ohio Corrupt Practices Act
Ohio Revised Code §§ 2923.31, *et seq.*
(Against Defendants Purdue, Cephalon, Endo, Mallinckrodt, Actavis,
McKesson, Cardinal and AmerisourceBergen)
(The “Opioid Supply Chain Enterprise”)**

7. The Fourth Claim for Relief is asserted against Defendants other than HBC and accordingly, no response to the averments contained in Paragraphs 950 through 973 of the Complaint is required.

FIFTH CLAIM FOR RELIEF

**Statutory Public Nuisance
(Against All Defendants)**

8. The averments contained in Paragraph 974 of the Complaint constitute an integration clause which requires no response. In the alternative, the responses set forth in Paragraphs 1 through 973 of the within Answer are incorporated herein as if restated in their entirety.

9. The averments contained in Paragraphs 974 through 996 of the Complaint are asserted against Defendant(s) other than HBC or denied for lack of knowledge or information sufficient to form a belief as to the truth of the averments, are conclusions of law to which no responsive pleading is required and/or are otherwise generally denied. By way of further answer,

it is averred that at all times material hereto, HBC acted in conformity with all applicable law and Plaintiffs are not entitled to any legal and/or equitable relief as requested in their Complaint.

SIXTH CLAIM FOR RELIEF

**Common Law Absolute Public Nuisance
(Against All Defendants)**

10. The averments contained in Paragraph 997 of the Complaint constitute an integration clause which requires no response. In the alternative, the responses set forth in Paragraphs 1 through 996 of the within Answer are incorporated herein as if restated in their entirety.

11. The averments contained in Paragraphs 998 through 1038 of the Complaint are asserted against Defendant(s) other than HBC or denied for lack of knowledge or information sufficient to form a belief as to the truth of the averments, are conclusions of law to which no responsive pleading is required and/or are otherwise generally denied. By way of further answer, it is averred that at all times material hereto, HBC acted in conformity with all applicable law and Plaintiffs are not entitled to any legal and/or equitable relief as requested in their Complaint.

SEVENTH CLAIM FOR RELIEF

**Negligence
(Against All Defendants)**

12. The averments contained in Paragraph 1039 of the Complaint constitute an integration clause which requires no response. In the alternative, the responses set forth in Paragraphs 1 through 1038 of the within Answer are incorporated herein as if restated in their entirety.

13. The averments contained in Paragraphs 1040 through 1071 of the Complaint are asserted against Defendant(s) other than HBC or are conclusions of law to which no responsive pleading is required and/or are otherwise generally denied. By way of further answer, it is

averred that at all times material hereto, HBC acted in conformity with all applicable law and Plaintiffs are not entitled to any legal and/or equitable relief as requested in their Complaint.

EIGHTH CLAIM FOR RELIEF

**Common Law Fraud
(Against the Marketing Defendants)**

14. The Eighth Claim for Relief is asserted against Defendants other than HBC and accordingly, no response to the averments contained in Paragraphs 1072 through 1089 of the Complaint is required.

NINTH CLAIM FOR RELIEF

**Injury Through Criminal Acts
(R.C. 2307.60)
(Against All Defendants)**

15. The averments contained in Paragraph 1090 of the Complaint constitute an integration clause which requires no response. In the alternative, the responses set forth in Paragraphs 1 through 1089 of the within Answer are incorporated herein as if restated in their entirety.

16. The averments contained in Paragraphs 1091 through 1107 of the Complaint are asserted against Defendant(s) other than HBC or are denied for lack of knowledge or information sufficient to form a belief as to the truth of the averments, are conclusions of law to which no responsive pleading is required and/or are otherwise generally denied. By way of further answer, it is averred that at all times material hereto, HBC acted in conformity with all applicable law and Plaintiffs are not entitled to any legal and/or equitable relief as requested in their Complaint.

TENTH CLAIM FOR RELIEF

**Unjust Enrichment
(Against All Defendants)**

17. The averments contained in Paragraph 1108 of the Complaint constitute an integration clause which requires no response. In the alternative, the responses set forth in Paragraphs 1 through 1107 of the within Answer are incorporated herein as if restated in their entirety.

18. The averments contained in Paragraphs 1109 through 1121 of the Complaint are asserted against Defendant(s) other than HBC or denied for lack of knowledge or information sufficient to form a belief as to the truth of the averments, are conclusions of law to which no responsive pleading is required and/or are otherwise generally denied. By way of further answer, it is averred that at all times material hereto, HBC acted in conformity with all applicable law and Plaintiffs are not entitled to any legal and/or equitable relief as requested in their Complaint.

ELEVENTH CLAIM FOR RELIEF

**Civil Conspiracy
(Against All Defendants)**

19. The averments contained in Paragraph 1122 of the Complaint constitute an integration clause which requires no response. In the alternative, the responses set forth in Paragraphs 1 through 1089 of the within Answer are incorporated herein as if restated in their entirety.

20. The averments contained in Paragraphs 1123 through 1136 of the Complaint are asserted against Defendant(s) other than HBC or are denied as conclusions of law to which no responsive pleading is required and/or are otherwise generally denied. By way of further answer, it is averred that at all times material hereto, HBC acted in conformity with all applicable law and Plaintiffs are not entitled to any legal and/or equitable relief as requested in their Complaint.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

1. Plaintiffs fail to state a claim against HBC upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

2. Plaintiffs fail to join one or more necessary and indispensable parties, including but not limited to: third parties that were allegedly injured; third parties that wrongfully diverted prescriptions; third parties that were responsible for the oversight and regulation of the manufacture and distribution of prescription opioids, including the DEA and the Ohio State Board of Pharmacy; and/or doctors and other medical practitioners that issued the prescriptions at issue.

THIRD AFFIRMATIVE DEFENSE

3. Plaintiffs' claims are barred in whole or in part by the applicable statute of limitations.

FOURTH AFFIRMATIVE DEFENSE

4. HBC did not owe or breach any common law, statutory or other duty to Plaintiffs. HBC appropriately, completely, and fully discharged any and all obligations and legal duties arising out of the matters alleged in the Complaint.

FIFTH AFFIRMATIVE DEFENSE

5. Plaintiffs lack standing, capacity and/or authority to assert their claims against HBC, including claims indirectly maintained on behalf of their citizens and claims brought as *parens patriae*. Plaintiffs' claims are barred, in whole or in part, because Plaintiffs have no private right of action under the relevant laws and regulations and/or Plaintiffs are not the real party in interest.

SIXTH AFFIRMATIVE DEFENSE

6. HBC did not proximately cause Plaintiffs' injuries and/or damages. Plaintiffs are unable to plead or prove that any act or failure to act of HBC, including with respect to the filling of opioid prescriptions and the design and operation of a system to detect and report suspicious orders, caused anybody any harm or resulted in any expenditures or damages by Plaintiffs. HBC denies all types of causation, including cause in fact, proximate cause, and producing cause, with respect to the claims asserted against HBC.

SEVENTH AFFIRMATIVE DEFENSE

7. Plaintiffs fail to allege a legally cognizable injury for their claims. Plaintiffs' alleged injuries are wholly derivative of alleged personal injuries of others and do not affect a "public right".

EIGHTH AFFIRMATIVE DEFENSE

8. Plaintiffs' claims are barred in whole or in part by the independent, intervening and/or superseding acts or failures to act of third parties, including but not limited to: the intentional and/or criminal acts of third parties; the intentional and/or criminal acts of doctors and other medical providers who issued the prescriptions at issue; and/or the intentional acts of third parties that were responsible for the oversight and regulation of the manufacture and distribution of prescription opioids, including the DEA and the Ohio State Board of Pharmacy. Such acts or failures to act were not reasonably foreseeable to HBC and HBC is not liable for such acts or failures to act, and HBC had no duty to prevent such acts. Any and all losses or claims allegedly sustained by Plaintiffs are the result of acts and/or omissions of persons over whom HBC does not, or did not, have any direction or control, and for whose actions or omissions HBC is not liable.

NINTH AFFIRMATIVE DEFENSE

9. Plaintiffs' claims are barred in whole or in part by Plaintiffs' comparative and/or contributory negligence, including but not limited to: Plaintiffs' superior knowledge of the alleged crisis, including Plaintiffs' access to detailed distribution and dispensing information through the OARRS database, access to law enforcement information and access to abuse and treatment information; Plaintiffs' failure to effectively enforce the law and prosecute violations thereof; Plaintiffs' own distribution and/or dispensing of prescription opioids by its own employees; and Plaintiffs' failure to communicate with Defendants with respect to the distribution and/or dispensing of prescription opioids.

TENTH AFFIRMATIVE DEFENSE

10. Plaintiffs' claims are preempted by federal law and/or Ohio law, including (without limitation) the federal Controlled Substances Act ("CSA") and the Food, Drug, and Cosmetic Act ("FDCA"), and they conflict with Congress' purposes and objectives in enacting relevant federal legislation and authorizing regulations, including the Hatch-Waxman amendments to the FDCA and implementing regulations. *See Geier v. Am. Honda Co.*, 529 U.S. 861 (2000). Plaintiffs' claims are barred, in whole or in part, by conflict preemption as set forth in the United States Supreme Court's decisions in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) and *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013).

ELEVENTH AFFIRMATIVE DEFENSE

11. Plaintiffs' tort claims, including common law and statutory public nuisance claims and negligence claims, are abrogated in whole or in part by the Ohio Product Liability Act.

TWELFTH AFFIRMATIVE DEFENSE

12. Plaintiffs' public nuisance claims are barred or limited because HBC did not unreasonably interfere with a public right. No action of HBC involved interference with real property; illegal conduct perpetrated by third parties involving the use of an otherwise legal product does not involve a public right against a self-distributor sufficient to state a claim for public nuisance; the alleged public nuisance would have impermissible extraterritorial reach; and the alleged conduct of HBC is too remote from the alleged injury as a matter of law and due process.

THIRTEENTH AFFIRMATIVE DEFENSE

13. Plaintiffs' claims are barred by the learned intermediary doctrine. All orders filled by HBC were only for Giant Eagle pharmacies which only ordered and dispensed controlled substances pursuant to prescriptions issued by adequately warned doctors and other authorized medical practitioners, which HBC and Giant Eagle had a duty to fill.

FOURTEENTH AFFIRMATIVE DEFENSE

14. HBC did not manufacture, advertise, promote or market any prescription opioids at any time. HBC is not liable for any statements or omissions in the Manufacturer Defendants' branded or unbranded materials, advertisements, promotions or marketing materials. Nobody relied to their detriment upon any statements by HBC in connection with the prescribing or use of opioids.

FIFTEENTH AFFIRMATIVE DEFENSE

15. HBC only distributed to affiliated Giant Eagle pharmacies and did not distribute prescription opioids or any other products to any third parties.

SIXTEENTH AFFIRMATIVE DEFENSE

16. At all relevant times HBC's DEA Distributor registration was limited to Schedule 3, 4 and 5 controlled substances. As a result, HBC never distributed Schedule 2 prescription opioids (the prescription opioids at issue in this case), and only self-distributed certain generic hydrocodone combination products ("HCPs") from November 2009 to October 2014 when HCPs were classified as Schedule 3 controlled substances. When HCPs were reclassified from Schedule 3 to Schedule 2 in approximately October of 2014 HBC stopped distributing HCPs and no longer distributed any opioids at issue in this case.

SEVENTEENTH AFFIRMATIVE DEFENSE

17. At all relevant times HBC substantially and/or fully complied with the DEA's security requirement set forth in Regulation §1301.71, including Regulation §1301.74(b), based upon its overall integrated system of controls at its warehouse facility, Giant Eagle corporate headquarters and Giant Eagle pharmacies. These controls were reasonable in light of, among other factors, the types and quantities of controlled substances it handled (never Schedule 2's, etc.), physical buildings and security systems and multiple other internal controls. The DEA's knowledge and audits of such systems and controls without any complaints or deficiencies further establishes their adequacy and compliance with the regulations.

EIGHTEENTH FIFTEENTH AFFIRMATIVE DEFENSE

18. Plaintiffs fail to state a claim against Giant Eagle and its affiliates, including the Giant Eagle Rx Distribution Center which is a separately licensed and separate distribution warehouse facility that opened in January of 2016 that has not been named as a defendant in any case.

NINETEENTH AFFIRMATIVE DEFENSE

19. Plaintiffs' claims are barred in whole or in part by the economic loss rule.

TWENTIETH AFFIRMATIVE DEFENSE

20. Plaintiffs' "Injury Through Criminal Acts" claim is barred by the absence of any criminal conviction and the absence of any injury to Plaintiffs' "person or property" and/or Defendants are "specifically excepted by law" from liability.

TWENTY-FIRST AFFIRMATIVE DEFENSE

21. Plaintiffs' unjust enrichment claim fails because Plaintiffs did not confer any benefit on HBC, HBC had no knowledge of any purported benefit conferred on HBC by Plaintiffs and/or it would not be unjust under the circumstances to deny Plaintiffs the ability to recover for social services it is supposed to provide to its residents.

TWENTY-SECOND AFFIRMATIVE DEFENSE

22. Plaintiffs' civil conspiracy claim fails because there is no "malicious combination" between HBC and any other defendant and there is no underlying unlawful act or intentional tort.

TWENTY-THIRD AFFIRMATIVE DEFENSE

23. Plaintiffs' claims are barred in whole or in part by the doctrines of unclean hands, waiver, estoppel, laches, acquiescence, ratification, consent, settlement, release and/or in *pari delicto*.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

24. Plaintiffs are barred from recovery by Plaintiffs' failure to mitigate damages.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

25. To the extent Plaintiff attempts to seek equitable relief, Plaintiffs are not entitled to such relief because Plaintiffs have an adequate remedy at law.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

26. Plaintiffs would be unjustly enriched if allowed to recover on any of their claims.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

27. To the extent that Plaintiffs seek punitive, exemplary, or aggravated damages, any such damages are barred because the product at issue, and its labeling, were subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

28. The damages which Plaintiffs may be entitled to recover if liability is established (which liability is specifically denied) are capped pursuant to Ohio Revised Code §§ 2315.18 and 2315.21.

TWENTY-NINTH AFFIRMATIVE DEFENSE

29. Plaintiffs' claims for punitive or exemplary damages are barred because Plaintiffs cannot prove by clear and convincing evidence that Defendant was grossly negligent and Defendant has neither acted nor failed to act in a manner that entitles Plaintiffs to recover punitive or exemplary damages.

THIRTIETH AFFIRMATIVE DEFENSE

30. Plaintiffs' claims for punitive or exemplary damages or other civil penalties are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Full Faith and Credit Clause of the United States Constitution, and applicable provisions of the Constitution of this State or that of any other state whose laws may apply. Any law, statute, or other authority purporting to permit the recovery of punitive damages or civil penalties in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining

whether to award punitive damages or civil penalties and/or the amount, if any; (2) is void for vagueness in that it fails to provide adequate notice as to what conduct will result in punitive damages or civil penalties; (3) unconstitutionally may permit recovery of punitive damages or civil penalties based on harms to third parties, out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiffs; (4) unconstitutionally may permit recovery of punitive damages or civil penalties in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiffs and to the amount of compensatory damages, if any; (5) unconstitutionally may permit jury consideration of net worth or other financial information relating to Defendant; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any award of punitive damages or civil penalties; (7) lacks constitutionally sufficient standards for appellate review of any award of punitive damages or civil penalties; (8) would unconstitutionally impose a penalty, criminal in nature, without according to Defendant the same procedural protections that are accorded to criminal defendant under the constitutions of the United States, this State, and any other state whose laws may apply; and (9) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991); *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of N. Am. v. Gore*, 517 U.S. 559 (1996); *State Farm Ins. Co. v. Campbell*, 538 U.S. 408 (2003); and *Philip Morris USA v. Williams*, 549 U.S. 346 (2007).

THIRTY-FIRST AFFIRMATIVE DEFENSE

31. Defendant's rights under the Due Process Clause of the U.S. Constitution and applicable state Constitution or statute are violated by any financial or other arrangement that might distort a government attorney's duty to pursue justice rather than his or her personal

interests, financial or otherwise, in the context of a civil enforcement proceeding, including by Plaintiffs' use of a contingency fee contract with private counsel.

THIRTY-SECOND AFFIRMATIVE DEFENSE

32. To the extent Plaintiffs are alleging fraud, fraudulent concealment, or similar conduct, Plaintiffs have failed to plead the allegations with sufficient particularity. Plaintiffs fail to plead any actionable misrepresentation or omission made by or attributable to Defendant. Plaintiffs' claims are barred in whole or in part because no conduct of Defendant was misleading, unfair, or deceptive.

THIRTY-THIRD AFFIRMATIVE DEFENSE

33. Plaintiffs' claims are barred, in whole or in part, by the free public services doctrine and/or the municipal cost recovery doctrine.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

34. Plaintiffs are barred from recovery against Defendant because Defendant complied with all applicable federal and Ohio State rules and regulations related to distribution of the subject prescription medications.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

35. Plaintiffs' claims and damages are barred or limited, in whole or in part, by common law, statutory, and state constitutional constraints on the exercise of police powers by a municipality.

THIRTY-SIXTH AFIRMATIVE DEFENSE

36. Plaintiffs are barred from recovery by application of the informed consent doctrine.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

37. Plaintiffs' claims are barred to the extent they are based on alleged violations of industry customs because purported industry customs do not create legal duties on Defendant.

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

38. Plaintiffs are barred or limited from recovery by the principles of assumption of risk, including that users of the medications at issue used them after they knew, or should have known, of their alleged risks.

THIRTY-NINTH AFFIRMATIVE DEFENSE

39. Plaintiffs' damages, if any, were caused by the active, direct, and proximate negligence or actual conduct of entities or persons other than Defendant, and in the event that Defendant is found to be liable to Plaintiffs, Defendant will be entitled to indemnification, contribution, and/or apportionment.

FORTIETH AFFIRMATIVE DEFENSE

40. Plaintiffs' claims are barred to the extent that the subject prescription medications were misused, modified, altered, or changed from the condition in which they were sold, which misuse, modification, alteration, or change caused or contributed to cause Plaintiffs' alleged injuries or damages, and over which HBC had no control.

FORTY-FIRST AFFIRMATIVE DEFENSE

41. HBC is not liable for any injuries or expenses allegedly incurred by Plaintiffs to the extent the injuries or expenses as alleged may have resulted from the pre-existing and/or unrelated medical conditions of the users of the subject prescription medications.

FORTY-SECOND AFFIRMATIVE DEFENSE

42. Plaintiffs may not recover against HBC because the methods, standards, or techniques of distributing of the subject prescription medications complied with and were in

conformity with the generally recognized state of the art at the time the product was designed, manufactured, labeled, and distributed. If Plaintiffs incurred the damages alleged, which is expressly denied, HBC is not liable for damages because the methods, standards, or techniques of designing, manufacturing, labeling, and distributing of the prescription medications at issue complied with and were in conformity with the laws and regulations of the Controlled Substances Act, the FDA and the FDCA, and the generally recognized state of the art in the industry at the time the product was designed, manufactured, labeled, and distributed.

FORTY-THIRD AFFIRMATIVE DEFENSE

43. Plaintiffs' claims are barred to the extent they are based on any allegations involving failure to provide adequate warnings or information because all warnings or information that accompanied the allegedly distributed products were approved by the United States Food & Drug Administration for a product approved under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Section 301 et seq.), as amended, or Section 351, Public Health Service Act (42 U.S.C. Section 262), as amended, or the warnings and information provided were those stated in monographs developed by the United States Food & Drug Administration for pharmaceutical products that may be distributed without an approved new drug application.

FORTY-FOURTH AFFIRMATIVE DEFENSE

44. Plaintiffs' claims are barred, in whole or in part, for failure to exhaust administrative remedies.

FORTY-FIFTH AFFIRMATIVE DEFENSE

45. Plaintiffs' claims are barred, in whole or in part, because federal agencies have exclusive or primary jurisdiction over the matters asserted in the Complaint.

FORTY-SIXTH AFFIRMATIVE DEFENSE

46. To the extent that Plaintiffs rely on letters or other informal guidance from the DEA to establish Defendant's regulatory duties, such informal guidance cannot enlarge Defendant's regulatory duties in the absence of compliance by DEA with the requirements by the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.*

FORTY-SEVENTH AFFIRMATIVE DEFENSE

47. Plaintiff's claims are barred in whole or in part because Plaintiff suffered no injuries or damages as a result of any action by HBC.

FORTY-EIGHTH AFFIRMATIVE DEFENSE

48. Plaintiffs' Complaint is barred, in whole or in part, because the derivative injury rule and the remoteness doctrine bar Plaintiffs from recovering payments that they allegedly made on behalf their residents to reimburse any expenses for health care, pharmaceutical care, and other public services. The alleged injuries and damages asserted by Plaintiffs are too remote and/or speculative from the alleged conduct of HBC to be a basis for liability as a matter of law and due process and derive solely from the claims of others. Plaintiffs, to the extent they are seeking any damages in their capacity as a third-party payor, cannot recover as damages the costs of healthcare provided to insureds.

FORTY-NINTH AFFIRMATIVE DEFENSE

49. Plaintiffs' claims are barred, reduced, and/or limited pursuant to the applicable Ohio statutory and common law regarding limitations of awards, caps on recovery, and setoffs. A specific percentage of the tortious conduct that proximately caused the injury or loss to person or property is attributable to one or more persons from whom Plaintiffs do not seek recovery in this action. Should HBC be held liable to Plaintiffs, which liability is specifically denied, HBC is entitled to a credit or set-off for all sums of money received or available from or on behalf of

any tortfeasor(s), by way of judgment or settlement, for the same injuries alleged in Plaintiffs' Complaint.

FIFTIETH AFFIRMATIVE DEFENSE

50. Plaintiffs' injuries, losses, or damages, if any, were caused by or contributed to by other persons or entities, whether named or not named as parties to this action, who may be jointly and severally liable for all or part of Plaintiffs' alleged injuries, losses, or damages, if any. HBC will request apportionment of the fault pursuant to Ohio Revised Code section 2307.23, *et seq.*, of all named parties to this action, whether or not they remain parties at trial. If HBC is found liable for Plaintiffs' alleged injuries and losses (which liability is specifically denied), HBC is liable only for its proportionate share of the damages that represent economic loss. Ohio Revised Code 2307.22.

FIFTY-FIRST AFFIRMATIVE DEFENSE

51. Any damages that Plaintiffs may recover against HBC must be reduced to the extent that Plaintiffs are seeking damages for alleged injuries or expenses related to the same user(s) of the subject prescription medications, or damages recovered or recoverable by other actual or potential plaintiffs. Any damages that Plaintiffs may recover against HBC must be reduced to the extent they unjustly enrich Plaintiffs.

FIFTY-SECOND AFFIRMATIVE DEFENSE

52. HBC's liability, if any, will not result from HBC's conduct but solely the result of an obligation imposed by law, and thus HBC is entitled to complete indemnity, express or implied, by other parties.

FIFTY-THIRD AFFIRMATIVE DEFENSE

53. To the extent that Plaintiffs seek relief for Defendant's conduct occurring before enactment of the applicable statutes or regulations, the claims fail because the statutes and regulations do not apply retroactively.

FIFTY-FOURTH AFFIRMATIVE DEFENSE

54. To the extent that Plaintiffs' claims relate to HBC's or other defendants' alleged advertising, public statements, lobbying, or other activities protected by the First Amendment to the Constitution of the United States or by the Constitution of the State of Ohio or that of any other state whose laws may apply, such claims are barred.

FIFTY-FIFTH AFFIRMATIVE DEFENSE

55. Plaintiffs' claims are barred to the extent that HBC has valid defenses which bar recovery by those persons on whose behalf Plaintiffs purportedly seek recovery.

FIFTY-SIXTH AFFIRMATIVE DEFENSE

56. HBC adopts by reference all defenses asserted in any party's motion to dismiss and/or answer filed herein. HBC asserts all applicable defenses under Federal Rules of Civil Procedure 8(c) and 12(b) and/or Ohio Rules of Civil Procedure 8(C) and 12(B), as investigation and discovery proceeds.

FIFTY-SEVENTH AFFIRMATIVE DEFENSE

57. The claims asserted in the Complaint are barred, in whole or in part, by the Restatement (Second) of Torts § 402A, Comments j and k, and Restatement (Third) of Torts: Products Liability § 6.

FIFTY-EIGHTH AFFIRMATIVE DEFENSE

58. Plaintiffs' claims are barred or limited by the political question and separation of powers doctrines and because this claim implicates issues of statewide importance that are reserved for state regulation.

FIFTY-NINTH AFFIRMATIVE DEFENSE

59. The claims asserted against HBC and other Defendants do not arise out of the same transactions or occurrences as required for joinder of parties.

SIXTIETH AFFIRMATIVE DEFENSE

60. Plaintiffs' claims are barred to the extent that they are based on a theory of market share liability.

SIXTY-FIRST AFFIRMATIVE DEFENSE

61. Plaintiffs' claims are barred to the extent that Plaintiffs' alleged damages are speculative, uncertain, and hypothetical.

SIXTY-SECOND AFFIRMATIVE DEFENSE

62. Plaintiffs' claims are not ripe, and/or have been mooted.

SIXTY-THIRD AFFIRMATIVE DEFENSE

63. HBC hereby gives notice that it reserves the right to rely upon any other applicable defenses set forth in any Answer of any other Defendant in this Action, reserves the right to rely upon any other defenses that may become apparent during fact of expert discovery in this matter, and reserves their right to amend their Answer and to assert any such defenses.

PRAYER FOR RELIEF

HBC denies that Plaintiffs are entitled to judgment or any relief, remedies or damages sought in their Prayer for Relief contained in Paragraph 1137 of the Complaint including the relief requested in subparagraphs a-1 of Paragraph 1137. HBC further denies any and all averments in Plaintiffs' Complaint not specifically admitted above. HBC requests that the Court enter judgment in its favor and against Plaintiffs on all Counts, award HBC its reasonable attorney's fees and costs with interest, and grant HBC any and all other appropriate legal and equitable relief the Court deems appropriate.

Dated: January 15, 2019

Respectfully submitted,

/s/ Robert M. Barnes
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CERTIFICATE OF SERVICE

I certify that on January 15, 2019, I electronically filed the foregoing document with the Clerk of the United States District Court, Northern District of Ohio. The electronic case filing system (CM/ECF) will send a Notice of Electronic Filing (NEF) to the attorneys of record who have consented in writing to accept this Notice as service of this document by electronic means.

/s/ Robert M. Barnes

Robert M. Barnes, Esq.